

April 3, 2015

The Honorable Karen DeSalvo, MD
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

ELECTRONICALLY SUBMITTED TO: www.healthit.gov/interoperability

RE: Comments on “Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0”

Dear Dr. DeSalvo:

On behalf of the Personal Connected Health Alliance (PCHA), formerly known as the Continua Health Alliance (Continua), we are writing to comment on the, “Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap DRAFT Version 1.0” (interoperability roadmap 1.0). PCHA appreciates the Office of the National Coordinator’s work to advance health information interoperability and implement the digital functionality into health care that is routine in other key sectors of our economy. Our comments focus on PCHA’s overarching public policy goals to:

- Promote use of open industry standards for interoperability of digital health information. This includes device interoperability in a manner that promotes patient health and provider efficiency as well as interoperability between EHRs.
- Advance HIT-enabled patient engagement and digital functionality through the sharing of patient generated health data in real time.

We urge you to speed adoption of policies and programs to facilitate services like remote patient monitoring and digitally enabled healthcare delivery that allow medical services to be delivered where patients live and work. Effective and efficient digitally enabled health care delivery includes, but is not limited to EHR functionality/interoperability. Rather, it must include a broader eco-system of digital information that supports patient care, patient engagement, and provider practices.

PCHA offers the following more specific comments in response to the question posed in the interoperability roadmap 1.0:

1. General

- a. *Are the actions proposed in the draft interoperability Roadmap the right actions to improve interoperability nationwide in the near term while working toward a learning health system in the long term?*
- b. *What, if any, gaps need to be addressed?*
- c. *Is the timing of specific actions appropriate?*
- d. *Are the right actors/stakeholders associated with critical actions?*

The Personal Connected Health Alliance (PCHA) is a global non-profit umbrella for Continua (an organization that develops consensus interoperability standards for personal connected health devices) and mHealth Summit. PCHA advocates for adoption and use of open industry standards for HIT interoperability. We believe that the actions and processes articulated as “Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability” are quite similar to the broadly understood components of open industry standards that are long-standing federal policy and that promote an effective and efficient technology and innovation marketplace. **We recommend that the Interoperability Roadmap 1.0 Critical Actions for a Coordinated Governance Framework and Process for Nationwide Health Information Interoperability refer to the OMB policy on open industry standards and implement the specific actions in the context of the OMB policy.**

We believe that coordinating ONC’s interoperability actions and processes with the OMB open industry standard policy will provide clarity and consistency to HIT interoperability activity. For health care, the adoption and use of open industry standards for interoperability: 1) follow long-standing and successful federal policy that has allowed the communications industry to flourish globally through ubiquitous interoperable mobile devices, systems, and networks, along with wired cable services and telephone systems, and 2) enable a systemic engagement approach of patients and other healthcare stakeholders. Simply, the open industry data policy provides a helpful roadmap and successful examples through which other industries achieved interoperability effectively and efficiently. According to the OMB Circular A-119¹:

“Many voluntary consensus standards are appropriate or adaptable for the Government’s purposes. The use of such standards, whenever practicable and appropriate, is intended to achieve the following goals:

- a. Eliminate the cost to the Government of developing its own standards and decrease the cost of goods procured and the burden of complying with agency regulation.
- b. Provide incentives and opportunities to establish standards that serve national needs.
- c. Encourage long-term growth for U.S. enterprises and promote efficiency and economic competition through harmonization of standards.
- d. Further the policy of reliance upon the private sector to supply Government needs for goods and services.”

¹ CIRCULAR NO. A-119 Revised, February 10, 1998, Accessed on 3/24/15 at https://www.whitehouse.gov/omb/circulars_a119/

2. Priority Use Cases

- a. *Appendix H lists the priority use cases submitted to ONC through public comment, listening sessions, and federal agency discussions. The list is too lengthy and needs further prioritization. Please submit 3 priority use cases from this list that should inform priorities for the development of technical standards, policies and implementation specifications.*

PCHA recommends that ONC prioritize the following three use cases that focus on patient engagement and patient reported health information:

20. Patients, families and caregivers are able to use their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records and use it or make it available to providers to support decision-making.

52. At-risk patients engage in healthcare monitoring programs which can detect life threatening situations (such as patient down and unresponsive) using at-home monitoring devices and electronic communications such as eVisits and telemedicine.

14. Patients routinely engage in healthcare encounters using electronic communications such as eVisits and telemedicine.

3. Governance

- a. *The draft interoperability roadmap includes a call to action for health IT stakeholders to come together to establish a coordinated governance process for nationwide interoperability. ONC would like to recognize and support this process once it is established. How can ONC best recognize and support the industry-led governance effort?*

ONC must engage and bring together the various industry-led, open industry HIT interoperability groups, it must identify those that follow open industry standards and guidelines so healthcare stakeholders know the range and scope of industry-led organizations exist, publish consensus standards, and certify interoperability. PCHA, through its participant organizations, operates an international, open, industry and government agency collective collaboration of healthcare, technology and medical device interests working together to improve the quality of healthcare through the use of interoperable telehealth, personal connected health, mobile health (mHealth), remote patient monitoring (RPM), and independent living technologies for what has been termed “e-Care” by the Federal Communications Commission. Working with a broad range of public and private sector industry leaders in the U.S. and internationally, Continua develops and implements consensus driven guidelines on interoperability that are made available publicly after pilot testing. Of particular note, key federal members who have or continue to collaborate on the development of Continua open industry interoperability guidelines include: the U.S. National Institute for Standards and Technology (NIST), the National Library of Medicine, the Department of Defense (via the US Army’s Telemedicine and Advanced

Technologies Research Center) and the Veteran's Administration (VA). Industry collaborations include HL7 and the IHE (Integrating the Healthcare Enterprise). Currently, Continua works with its public and private sector members to develop, test, and release its Design Guidelines, the most recent of which were released in 2014. Guidelines detail the commercial standards and specifications that Continua selected for ensuring interoperability of devices, systems and services. These guidelines are specifically written for implementation by device manufacturers with the intent to put their devices through the Continua Certification process, thereby integrating Continua devices into their systems and subsystems, and working with global test labs to certify Continua certification.

ONC should identify Continua, and all other open industry-led interoperability organizations, as models and means by which interoperability may be achieved and tested.

Additionally, we note that Continua certification is identified by several international health care systems as a means to achieve interoperability. These international health care systems include:

- ✓ **Norway²**
- ✓ **Denmark³**

Continua would be delighted to introduce ONC to expert government staff in each of these countries where Continua Certification is a recognized means to achieve interoperability and provide introductions in other countries where Continua is engaged, although not yet officially recognized.

5. Privacy and Security Protections for Health Information

- a. What security aspects of RESTful services need to be addressed in a standardized manner?*

Continua Health Alliance Certification plays a key role in defining privacy and security for Personal Connected Health and is leading/driving underlying SDOs and standards to ensure that privacy and security regulations and requirements as well as security threats are addressed across Continua end to end architecture. Where regulations, requirements and security threats are not adequate Continua adds additional requirements to its guidelines for implementers ensuring privacy and security across the end to end interfaces and **verifies compliance via certification testing.**

² see: <https://www.regjeringen.no/en/aktuelt/standardisering-av-velferdsteknologi-med-continua/id2356200/>

³ see: http://www.ssi.dk/English/HealthdataandICT/~/_media/Indhold/DK%20-%20dansk/Sundhedsdata%20og%20it/NationalSundhedsIt/English/telemedicinENG.ashx

The 2015 Continua Design Guidelines (CDG), currently in public review and comment phase, include and update a REST Interface based on HL7's hData Record Format. The next version of the CDG is undergoing work now to incorporate HL7's FHIR-based RESTful framework. Continua technical experts and staff would be delighted to provide ONC a briefing on how it incorporates the REST Interface in the CDG as well as verifies compliance via certification. Continua's open industry standard process combined with its use of the REST Interface offers ONC an excellent example of both use the REST Interface in a standard manner in the context of industry led and open standard development.

We appreciate the opportunity to provide comments on the Interoperability Roadmap 1.0 and are excited that ONC is developing an approach in which industry-led consensus interoperability standards, like those identified, tested, and certified by Continua. Patients need and expect our health care system to operate with 21st century technology that enables patient provider electronic communication.

Please contact me if you need any additional information or have questions. PCHA welcomes the opportunity to work with ONC as these and other exciting regulatory and policy changes are under consideration.

Sincerely,



Rob Havasy
Vice President, Personal Connected Health Alliance
Executive Director, Continua Health Alliance